DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2014

Home Dialysis Plus
Nancy Gallo
Senior Vice President, Regulatory Affairs
257 Humboldt Court
Sunnyvale, CA 94089

Re: K140866
Trade/Device Name: Tablo Console
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: August 1, 2014
Received: August 4, 2014

Dear Nancy Gallo,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140866

Device Name
Tablo Console

Indications for Use *(Describe)*
The Tablo™ System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription, with a trained individual available as needed who is considered competent in the use of the device by the prescribing physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

5.1 Submitter's Information

Submitter's Name: Company: Address:	Moshe Pinto, CEO HDPlus 257 Humboldt Ct, Sunnyvale, CA 94089
Contact Person:	Nancy Gallo, Senior Vice-President, Regulatory Affairs
Phone:	510.682.6505
Facsimile:	408.329.9091
Email:	ngallo@homedialysisplus.com
Date of Summary Preparation:	March 31, 2014

5.2 Device Information

Trade Name:	Tablo™ Console	
Common Name:	Hemodialysis Delivery System	Portable Water Treatment System
Classification Name:	High Permeability Hemodialysis Delivery System	Water Purification System for Hemodialysis
Classification Number:	Class II per 21 CFR 876.5860	Class II per 21 CFR 876.5665
Product Code:	KDI	FIP
Classification Panel:	Gastroenterology/Urology	Gastroenterology/Urology

5.3 Predicate Device Information

Fresenius 2008T Hemodialysis Machine (K120505)
Lauer Aquaboss EcoRO Dia 50 (K032004)

5.4 Device Description

The Tablo™ Console is a self-contained hemodialysis system (Console) intended for acute and chronic dialysis therapy with or without ultrafiltration. The Tablo Console consists of a conventional Dialysis Delivery System (DDS; Upper Module) and a compact Water Purification System (WPS; Lower Module). The Dialysis Delivery System (Upper Module) and the Water Purification System (Lower Module) are stacked and latched together to form a single integrated Console.

5.5 Indications for Use

The Tablo System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription, with a trained individual available as needed who is considered competent in the use of the device by the prescribing physician.

5.6 Technological Characteristics

The Tablo Console (Subject Device) utilizes two Predicate Devices; Fresenius 2008T (K120505) for the Upper Module and Lauer Aquaboss EcoRO Dia 50 (K032004) for the Lower Module.

5.6.1 Tablo Console (Upper Module) vs. Fresenius 2008T (K120505)

The Tablo Console (Upper Module) and the Predicate Device are equivalent in technological characteristics:

- Intended use - To deliver hemodialysis to patients with renal disease.
- Off the shelf components - Dialyzers and non-invasive blood pressure cuffs (NIBP).
- Standards - Electrical and electromagnetic safety, and Hemodialysis System standards.
- Software - Software controlled, and utilize Graphic User Interface (GUI).
- Design and Construction – Blood pump, heparin pump, alarms, alerts, air detector mechanism, and blood leak detectors.
- Disinfection - Heat and chemical disinfection.

Minor differences exist in the technological characteristics of the Subject and Predicate Devices. None of the minor differences raise any new or different questions of safety or effectiveness. The differences include:

- Compatibility - The Tablo Console (Subject Device) was developed to interface with a specific Blood Tubing Set (i.e. the Tablo Cartridge), whereas the Predicate is universal in this respect.
- System level specifications - The Tablo Console and the Predicate differ in certain system level specifications like the blood and dialysate flow rates, ultrafiltration rate, dialysate temperature range, Acid and Bicarbonate concentration, ratio of mixture, and pressure ranges.
- Electromagnetic Safety Rating for RF emissions - The rating for the Subject Device is Class B while the Predicate Device is Class A.

5.6.2 Tablo Console (Lower Module) vs. Aquaboss EcoRO Dia 50 (K032004)

The Tablo Console (Upper Module) and the Predicate Device are equivalent in technological characteristics:

- Intended use - To produce hemodialysis quality water.
- Water Purification Method – Reverse Osmosis.
- Standards – Water for hemodialysis, and electrical and electromagnetic safety standards.

- Software - Software controlled, and utilize a user interface.
- Design and Construction – Carbon, sediment, and RO filters.

Minor differences exist in the technological characteristics of the Subject and Predicate Devices. None of the minor differences raise any new or different questions of safety or effectiveness. The differences include:

- Disinfection Method - The Tablo Console utilizes both Heat and Chemical Disinfections whereas the Predicate utilizes only Chemical Disinfection.
- Components – The Subject Device incorporates a Pre Filter and Heat Exchanger whereas the Predicate Device does not.

5.7 Performance Data

The following Performance Testing, developed in accordance with appropriate FDA guidance documents and relevant standards, has been performed on the Subject Device to support the determination of substantial equivalence:

- Performance testing for heat and chemical disinfections, treated water quality, dialysate quality, and all the key functions/design features/components.
- Testing to confirm compliance with electrical and electromagnetic safety standards and performance of alarms and alerts.
- Performance testing for software and the touchscreen.
- Testing of the fluid path materials.

5.8 Conclusion

The Performance Testing demonstrates that the Tablo Console meets all performance specifications, complies with applicable standards and FDA Guidance Documents. The Tablo Console is substantially equivalent to the Predicate Devices, and the minor differences in the technological characteristics of the Subject and the Predicate Devices do not raise any new or different questions of safety or effectiveness.